1600 (8A1) NEC 1642

Docket No.: PC-0039 US

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By: _____ Printed: Katherine Stofer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Chen et al.

Title: MUCIN-RELATED TUMOR MARKER

Serial No.: 09/840,746 Filing Date: April 23, 2001

Examiner: Davis, M. Group Art Unit: 1642

Box Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL FEE SHEET

Sir:

Transmitted herewith are the following for the above-identified application:

1. Return Receipt Postcard; and
2. Response to Restriction Requirement (4 pp.).

The fee has been calculated as shown below.

Claims	Claims After Amendment		Claims Previously Paid For		Present Extra	Other Than Small Entity Rate	Fee		Additional Fee(s)
Total	6	-	20		0	x$18.00		$	0
Indept.	2	-	3		0	x$84.00		$	0
First Presentation of Multiple Dependent Claims						+280.00		$	0
							Total Fee:	$	0

X No additional Fee is required.

___ Please charge Deposit Account No. **09-0108** in the amount of : $ _____

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17, or credit overpayment to Deposit Account No. 09-0108. **A duplicate copy of this sheet is enclosed.**

Respectfully submitted,

INCYTE GENOMICS, INC.

Date: June 13, 2002

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Title: MUCIN-RELATED TUMOR MARKER

Serial No.:	09/840,746	Filing Date:	April 23, 2001
Examiner:	Davis, M.	Group Art Unit:	1642

Box Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. 121

Sir:

This paper is responsive to the Restriction Requirement and Request for Election dated May 23, 2002, setting a one (1) month term for response. Claims 1-20 were originally filed. In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims1-6) drawn to an isolated cDNA comprising SEQ ID NO:2, or an isolated cDNA encoding SEQ ID NO:1, fragments thereof of SEQ ID NOs:3-18, a vector, host cell, and a method for producing a protein.

Group II (claims 7 and 9) drawn to a method for detecting the expression of a nucleic acid using Northern hybridization.

Group III (claim 8) drawn to a method for detecting the expression of a nucleic acid using PCR.

Group IV (claim 10) drawn to a method for detecting breast cancer using Northern hybridization.

Group V (claims 11-12) drawn to a method for screening a plurality of molecules or compounds that bind the cDNA of SEQ ID NO:2.

Group VI (claims 13-14) drawn to a protein of SEQ ID NO:1.

Group VII (claims 15-16) drawn to a method for screening a plurality of molecules or compounds

that bind SEQ ID NO:1.

Group VIII (claim 17) drawn to a method for producing an antibody specific for SEQ ID NO:1.

Group IX (claim 18) drawn to an antibody specific for SEQ ID NO:1.

Group X (claims 19-20) drawn to a method for detecting conditions associated with expression of a protein or breast cancer.

The Examiner further required that upon election of Group I, the further election of the following patentably distinct species: The full length sequence or fragments thereof. Upon election of fragments, election from SEQ ID NOs:3-18. Upon election of Group V, further election from DNA molecules, RNA molecules, peptide nucleic acids, artificial chromosome constructions, peptides, transcription factors, repressors, and regulatory molecules, wherein regulatory molecules are generic to transcription factors and repressors. Upon election of Group VII, further election from 1) DNA molecules, 2) RNA molecules, 3) peptide nucleic acids, 4) peptides, 5) proteins, 6) mimetics, 7) agonists, antibodies or immunoglobulins, wherein agonists are generic to antibodies, 8) antagonists, or inhibitors, antibodies or immunoglobulins, wherein antagonists or inhibitors are generic to antibodies, and 9) drugs.

Applicants hereby elect, with traverse, to prosecute Group I, which includes and is drawn to Claims 1-6. Within Group I, Applicants further elect the full length sequence of polynucleotides encoding SEQ ID NO:1, including SEQ ID NO:2, again with traverse. Applicants object to the excessive restriction of claimed subject matter, particularly with respect to the species restriction within various groups and methods of use the claimed polynucleotides. The Examiner is respectfully reminded that proper restriction requires the following two conditions be met according to MPEP 803:

Restriction-When Proper:

> There are two criteria for a proper requirement for restriction between patentably distinct inventions:
>
> (A) The inventions must be independent (see MPEP Section 802.01 Section 806.04, Section 808.01) or distinct as claimed (see MPEP Section 806.05 - Section 806.05(i)); and
>
> (B) There must be a serious burden on the examiner if restriction is required (see MPEP Section 803.02 Section 806.04(a) - Section 806.04(i), Section 808.01(a), and Section 808.02). (Emphasis added).

While the first element (A) of this requirement may be fulfilled in the present restriction, the second clearly has not. The Examiner has not presented any evidence that the examination of SEQ ID NOs:3-18, which are acknowledged by the Examiner to be component fragments of the full length sequence of SEQ ID NO:2, would pose an additional serious burden of search. Clearly, these sequences would be found in a search for SEQ ID NO:2, and variants having at least 90% sequence identity to SEQ ID NO:2. In addition, the restriction of claims 7-12, reciting methods of use of the polynucleotides of

Group I into separate groups is also inappropriate because, as noted by the Examiner, Groups II, IV and V are classified the same (e.g., class 435, and specifically subclass 6) and would therefore involve the same search. Furthermore, the limitation in claim 8 requiring PCR amplification of the nucleic acid prior to detection by hybridization as recited in claim 7, does not represent a separate method of detection as implied by the Examiner. Since the methods of claims 7-12 also depend from and are of the same scope as the polynucleotides of Group I, Applicants further submit that they could be examined together with the composition of matter claims from which they depend, again without undue burden. Finally, the Examiner's request for election of a single molecule or compound in Groups V and VII misrepresents the concept of election of species. Applicants submit that the patentable distinctiveness of the molecules or compounds recited in the claims are not an issue for examination purposes as the claims are to a method of use of the compositions of Groups I and not to the species themselves.

Applicants therefore request reconsideration of the Restriction Requirement and examination of claims 1-12 in Groups I-V with respect to all species recited. In the event that the Examiner maintains the Restriction Requirement, the Examiner is reminded that claims 7-12 of Groups II-V are methods of use of the compositions of Group I that depend from and are of the same scope as the claims of Group I, and are subject to rejoinder on allowance of the claims of Group I in accordance with *Ochiai and Brouwer* regardless of their restriction (see Commissioner's Notice in the Official Gazette of March 26, 1996). Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,

INCYTE GENOMICS, INC.

Date: June 13, 2002

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